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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,285	01/24/2002	Meir Rosenberg	022719-0025	8551

7590 12/28/2004

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One International Place  
Boston, MA 02210-2699

EXAMINER
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BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/056,285	Applicant(s) ROSENBERG, MEIR	
	Examiner Patricia M Bianco	Art Unit 3762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 September 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-23 is/are allowed.
- 6) ☒ Claim(s) 1-3 and 11-16 is/are rejected.
- 7) ☒ Claim(s) 4-10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Final Rejection</u> .                  |

## DETAILED ACTION

### *Response to Amendment*

In the amendment filed 9/28/04, claim 1 was amended. Claims 1-23 are currently pending.

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. The following embodiments of the bellows must be shown or the feature(s) canceled from the claim(s), wherein the bellows comprises one of the following (as claimed in claims 11-14): **flexible bellows, programmable spring mechanism, leaf spring, coiled spring, and helical spring.**

No new matter should be entered. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct

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any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, & 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lecuyer (5,437,627) in view of Cosman (4,787,886) and in further view of Wellner et al. (4,413,985). Lecuyer discloses a shunt having a housing 12+14 defining a first 18 and a second 20 chamber, an inlet port 38 and an outlet port 44, and a valve mechanism which is a flexible diaphragm 16 and valving piece 24, which is defined by a valve seat 26. The diaphragm has a fluid flow orifice 22, which receives the valving piece 24 and a spherical member 28, which acts as a blocking member. A coiled spring 30, or biasing element, provides a force or pressure against the spherical member. Lecuyer does not disclose that the shunt has a pressure sensor, nor specifically that the spherical member 28 (i.e. blocking element) has a first surface and a second surface, each having an area that is substantially equal to the other.

Cosman teaches of shunt devices including a pressure sensor for measuring pressure outside of the shunt. It would have been obvious to one having ordinary skill

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in the art at the time the invention was made to modify the shunt device of Lecuyer, as taught by Cosman in order to monitor the pressure outside the shunt to ensure that the drainage is proper.

Wellner et al. discloses a hydrocephalus shunt having a ball a ball valve 24 that act as a blocking member, and has a spring 23 that acts upon said ball valve acting as a biasing element. As shown in figure 4, the ball valve has a first surface and a second surface, wherein the surface areas are substantially equal to one another. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shunt device of Lecuyer, as taught by Wellner to modify the size of the valving piece and the size of the spring to result in the valving piece having a first surface and a second surface, wherein the surface areas are substantially equal to one another, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Lecuyer, Cosman & Wellner substantially discloses the claimed invention except for having the spring (biasing element) be programmable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to automate the spring's exertion of force, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

***Allowable Subject Matter***

Claims 17-23 are allowed. The subject matter of the independent claim could either not be found or was not suggested in the prior art of record. The subject matter not found was the pressure sensor comprising a vent port on the housing, wherein the vent port has a conformable membrane surrounded by a reference pressure chamber in combination with the other elements (or steps) in the claims.

Claims 4-10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The subject matter not found was the pressure sensor comprising a vent port on the housing, wherein the vent port has a conformable membrane surrounded by a reference pressure chamber in combination with the other elements (or steps) in the claims. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application.

***Response to Arguments***

Applicant's arguments with respect to the art rejection of claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

The drawing objection has been maintained. Applicant argues that new drawings are not necessary, basing his arguments on 35 U.S.C. §113, first sentence. However, the copy of the rules the examiner is relying upon states, for 35 U.S.C. §113, that this rule deals with the final rejection or action. Nothing with respect to rule 35 U.S.C. §113

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discusses the drawing requirements. However, rule 35 U.S.C. §1.83(a) states, in part, that "the drawing in a nonprovisional application must show every feature of the invention specified in the claims." The objection to the drawings will not be held in abeyance.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (571)

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272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 21<sup>st</sup>, 2004

Patricia M Bianco  
Primary Examiner  
Art Unit 3762

  
**PATRICIA BIANCO**  
**PRIMARY EXAMINER**